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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/833,245	04/12/2001	Craig A. Rosen	6832.0018-00	3724

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EXAMINER

BORIN, MICHAEL L

ART UNIT	PAPER NUMBER
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1631

DATE MAILED: 06/16/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

## Office Action Summary

Application No.

09/833,245

Applicant(s)

ROSEN ET AL.

Examiner

Michael Borin

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --  
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

### Status

- 1) ☒ Responsive to communication(s) filed on 03/08/2005.  
2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.  
3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

### Disposition of Claims

- 4) ☒ Claim(s) 1-4, 13-17, 19, 20 and 30-33 is/are pending in the application.  
4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.  
5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.  
6) ☒ Claim(s) 1-4, 13-17, 19, 20 and 30-33 is/are rejected.  
7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.  
8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

### Application Papers

- 9) ☐ The specification is objected to by the Examiner.  
10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).  
11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

### Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).  
a) ☐ All b) ☐ Some \* c) ☐ None of:  
1. ☐ Certified copies of the priority documents have been received.  
2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.  
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).  
\* See the attached detailed Office action for a list of the certified copies not received.

### Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892)  
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)  
3) ☒ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)  
Paper No(s)/Mail Date 2 IDSs.  
4) ☐ Interview Summary (PTO-413)  
Paper No(s)/Mail Date. \_\_\_\_\_.  
5) ☐ Notice of Informal Patent Application (PTO-152)  
6) ☐ Other: \_\_\_\_\_.

## **DETAILED ACTION**

### ***Status of Claims***

Claims 1-4,13-17,19,20,30-33 are pending.<sup>1</sup>

Response to restriction requirement filed 02/16/05 is acknowledged. Applicant elected, with traverse, "protein encoded by HEMCM42" as the therapeutic protein. Applicant argues that there will not be serious burden of search. Examiner respectfully disagrees and points out that claims as amended at the time of restriction requirement have read on 2277 compounds of unrelated products. The restriction requirement is still deemed proper and is therefore made FINAL. The issue is moot, however, as applicant amended claims to read only on protein encoded by HEMCM42.

### ***Information Disclosure Statement***

Applicants' Information Disclosure Statements filed 08/12/2004 and 02/16/2005 have been received and entered into the application. Completed copies of forms PTO-1449 are attached.

This case presented a situation where the Information Disclosure Statements are in excess of 70 pages. A cursory glance at the M.P.E.P. 2004, subsection entitled "Aids to Compliance With Duty of Disclosure," item thirteen states:

It is desirable to avoid the submission of long lists of documents if it can be avoided. Eliminate clearly irrelevant information and marginally pertinent cumulative information. If a long list is submitted, highlight those documents

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<sup>1</sup> Examiner apologizes for inadvertent exclusion of claims 19,20 from the list of pending claims in the previous restriction requirement.

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which have been specifically brought to Applicant's attention and/or are known to be of the most significance.

As none of the information that has been cited by Applicants has been identified as being relevant or material for patentability of the elected subject matter, Examiner made only cursory examination of presented documents.

### ***Incorporation by reference***

It is noticed that applicant incorporates by reference the entire content of more than 900 patent application (pages 513-533 of specification). In view of election of Group I, claims 1-4,13-20, drawn to conjugates of albumin, applicant is requested to provide a list of the applications from the above list that are related to the elected subject matter.

Further, as applicant does not specify that the information in the cited exhaustive list of references is essential, it is deemed to refer to non-essential subject matter.

Furthermore, applicant's attention is directed to MPEP 608.01(p) which instructs:

Mere reference to another application, patent, or publication is not an incorporation of anything therein into the application containing such reference for the purpose of the disclosure required by 35 U.S.C. 112, first paragraph. In re de Seversky, 474 F.2d 671, 177 USPQ 144 (CCPA 1973). In addition to other requirements for an application, the referencing application should include an identification of the referenced patent, application, or publication. Particular attention should be directed to specific portions of the referenced document where the subject matter being incorporated may be found.

***Claim Rejections - 35 USC § 112, second paragraph.***

The following is a quotation of the second paragraph of 35 U.S.C. 112:  
The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 1-4,13-17,19,20,30-33 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. The claims are amended to read on protein encoded by HEMCM42. The definition of "protein encoded by HEMCM42" is vague and unclear as "HEMCM42" is not defined either in the claims or in specification. There is no sequence associated with this abbreviation. Note, that attempt to incorporate by reference entire content of more than 900 patent application, one of which addresses now claimed HEMCM42 (Table, p. 59) is improper because it is essential material and incorporation of essential material in the specification by reference to a foreign application or patent, or to a publication is improper.

***Claim Rejections - 35 U.S.C. § 101/ 112-1***

Claims 1-4,13-17,19,20,30-33 are rejected under 35 U.S.C. § 101 because the claimed invention is not supported by either a specific and substantial asserted utility or a well established utility. The claims are drawn to "protein encoded by HEMCM42". There is no information regarding the nature of nucleic acid abbreviated as "HEMCM42", nor there is any indication regarding utility of the particular "protein encoded by HEMCM42". The specification does not relate to any "real world" substantial utility of the claimed product.

Claims 1-4,13-17,19,20,30-33 are also rejected under 35 U.S.C. §112, first paragraph. Specifically, since the claimed invention is not supported by either a credible asserted utility or a well established utility, one skilled in the art would not know how to use the claimed invention.

***Claim Rejections - 35 USC § 112, first paragraph.***

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 1-4,13-17,19,20,30-33 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the enablement requirement. The claims are amended to read on protein encoded by HEMCM42. The definition of "protein encoded by HEMCM42" is vague and unclear as "HEMCM42" is not defined either in the claims or in specification. There is no sequence associated with this abbreviation. Therefore,

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the claims contains subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make the invention. Note, that attempt to incorporate by reference entire content of more than 900 patent application, one of which addresses now claimed HEMCM42 (Table, p. 59) is improper because it is essential material and incorporation of essential material in the specification by reference to a foreign application or patent, or to a publication is improper.

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO MONTHS** of the mailing date of this final action and the advisory action is not mailed until after the end of the **THREE-MONTH** shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than **SIX MONTHS** from the date of this final action.

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Any inquiry concerning this communication or earlier communications from the examiner should be directed to Michael Borin whose telephone number is (571) 272-0713. The examiner can normally be reached on 9am-5pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Ardin Marschel, Ph.D, can be reached on (571) 272-0718. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Michael Borin, Ph.D.

Primary Examiner

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A handwritten signature in black ink, appearing to read 'Michael Borin', is written over a diagonal line that extends from the signature area towards the 'Primary Examiner' text.

mlb